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No. 06-1249

IN THE

Supreme Court of the United States

WYETH,

Petitioner,

v.

DIANA LEVINE,

Respondent.

On Writ of Certiorari to the Vermont Supreme Court

BRIEF FOR THE AMERICAN ASSOCIATION FOR JUSTICE AS AMICUS CURIAE SUPPORTING RESPONDENT

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INTEREST OF AMICUS CURIAE

The American Association for Justice ("AAJ"), formerly the Association of Trial Lawyers of America, respectfully submits this brief as *amicus curiae* in support of Respondent. This brief is filed with consent of all parties.[1]

AAJ is a voluntary national bar association whose trial lawyer members primarily represent individual plaintiffs in personal injury cases and other civil actions, including product liability cases. Throughout its history, AAJ has advocated in courts, in Congress, and in state legislatures to preserve the protections for ordinary citizens afforded by the common law and to ensure that state tort claims, such as product liability claims, provide injured persons with effective legal recourse and remedies for wrongful injuries. By bringing such claims on behalf of people injured by drug products and by testifying before Congress about drug safety and the FDCA, AAJ's members have helped to ensure that the nation's consumers have access to safe and effective pharmaceuticals.

SUMMARY OF ARGUMENT

A common law cause of action against drug manufacturers for failure to provide adequate warnings has been recognized for over 150 years and has coexisted with federal regulation for a century.

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[1] Letters of consent from both parties have been filed with the Clerk of Court. Pursuant to Rule 37.6, *amicus* states that no counsel for a party authored any part of this brief, nor did any person or entity other than *amicus*, its members, or its counsel make a monetary contribution to its preparation or submission.

Congress, through multiple revisions of the Food, Drug, and Cosmetic Act, has consistently declined to preempt such state tort litigation. For good reasons Congress and, until recently, the FDA viewed state tort liability as an important complement to federal regulation in ensuring safe and effective drugs.

State tort law has always taken a drug company's compliance with FDA requirements into account as evidence that the company was not negligent. Once a defendant demonstrates such compliance, the plaintiff must come forward with evidence that a reasonable company would have done more under the circumstances, as Diana Levine did in this case. This focus on the special circumstances of the case ensures that a finding of liability will not pose a "direct and positive conflict" with FDA regulatory decisions.

Virtually every state and Congress has declined to elevate compliance with FDA requirements into a dispositive defense. They recognize that such a defense would be difficult to apply, place excessive reliance on the FDA, undermine incentives for drug companies to strengthen their warnings, and leave injured persons remediless. This Court must not now create a national FDA compliance affirmative defense under the guise of implied conflict preemption.

ARGUMENT

I. Federal Regulation of Prescription Drugs and State Tort Liability for Inadequate Warnings Have Coexisted Compatibly For a Century.

A. A Common Law Cause of Action for Failure to Warn of the Risks Posed by Drugs is Long-Standing and Widely Recognized.

A common law cause of action for negligence with respect to the manufacture, sale, and administration of medicines and related products predates federal regulation of pharmaceuticals and is widely recognized and accepted. *See Thomas v. Winchester*, 6 N.Y. 397, 1852 WL 4748 (N.Y. 1852) (holding a drug manufacturer who carelessly labeled a poison as a harmless medicine and sold the mislabeled medicine liable for a patient's resultant injury). Where, as here, there has been a "long history of tort litigation" in the area of state common law at issue, the presumption against preemption has "add[ed] force." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005).

State courts have held drug manufacturers liable for injuries resulting from failures to adequately warn of the risks and potential side-effects associated with their products since at least the mid-nineteenth century. *See, e.g. Norton v. Sewall*, 106 Mass. 143, 1870 WL 3529 (Mass. Nov. 1870); *Blood Balm Co. v. Cooper*, 83 Ga. 457, 10 S.E. 118 (Ga. 1889); *Peters v. Johnson*, 50 W. Va. 644, 41 S.E. 190 (W. Va. 1902). In *Thomas v. Winchester*, for example, the court held that, although the drug

manufacturer's "sale of the poisonous article was made to a dealer in drugs, and not to a consumer," the manufacturer had a duty to the ultimate consumer to warn of possible risks attendant to the drug and to adequately label the drug:

> The defendant's duty [to the consumer] arose out of the nature of his business and the danger to others incident to its mismanagement. Nothing but mischief like that which actually happened could have been expected from sending the poison falsely labeled into the market; and the defendant is justly responsible for the probable consequences of the act.

1852 WL 4748, at *9.

Congress first regulated food and drugs in the Federal Food and Drugs Act of 1906, 21 U.S.C. §§ 1, *et seq*. The 1906 act was intended to "prevent the misuse of the facilities of interstate commerce in conveying to and placing before the consumer misbranded and adulterated articles of medicine or food . . . ." *McDermott v. Wisconsin*, 228 U.S. 115, 131 (1913). Congress did not address state tort liability in the 1906 act, implicitly indicating that it did not intend to restrict such well-established causes of action, which furthered the purposes of the act by providing remedies for persons who wrongly suffered drug-related injuries. As this Court explained only a few years after the statute was enacted, "it by no means follows that the state is not permitted to make regulations, with a view to the protection of its people against fraud or imposition by impure food or drugs." *Id.*

After the 1906 act was enacted, common law failure to warn litigation continued unconstrained. *See, e.g., Hruska v. Parke, Davis & Co.*, 6 F.2d 536 (8th Cir. 1925) (holding that a manufacturer's negligence in preparing or selling a pharmaceutical product is actionable by a consumer or third party who suffers from the negligence); *Marigny v. Dejoie*, 172 So. 808 (La. Ct. App. 1937) (holding pharmacist liable for plaintiff's injuries resulting from ingestion of mislabeled drug); *Boyd v. Coca Cola Bottling Works*, 177 S.W. 80, 81 (Tenn. 1915) (holding that drug, food, and beverage manufacturers owe a duty to those who consume their products and that "[a] tort is committed, a legal right invaded, by practices which prejudice another's health"); *see also Mazetti v. Armour & Co.*, 135 P. 633 (Wash. 1913) (holding that restauranteur could bring action against food manufacturer when restaurant patron was injured by manufacturer's product, which was regulated by, and violated, the 1906 act). During this period, various states also enacted complementary laws to "provide the particular consumer and the general public with a higher and surer degree of protection than is afforded by exclusive recourse to common-law remedies." *McClanahan v. California Spray-Chem. Corp.*, 75 S.E.2d 712, 717-18 (Va. 1953) (discussing 1906 act and subsequently enacted state laws).

Congress revisited, and strengthened, federal regulation of food and drugs in 1938, when it enacted the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392 ("FDCA"). Congress did not attempt to limit the state tort liability of pharmaceutical manufacturers in the FDCA, or in any of its subsequent amendments, as discussed below. *See infra* at 5-6.

Moreover, even after the enactment of the FDCA, persons injured by prescription drugs continued to sue drug companies for inadequate warnings. *See Riegel v. Medtronic*, ___ U.S. ___, 128 S.Ct. 999, 1017 (2008) (Ginsburg, J., dissenting) (from passage of FDCA through 1976 Medical Device Amendments, "state common-law claims for drug labeling and design defects had continued unabated"); *see, e.g., Marcus v. Specific Pharms., Inc.*, 82 N.Y.S.2d 194, 194 (N.Y. Sup. Ct. 1948) (denying drug company's motion to dismiss failure-to-warn claims, because "[o]ne who manufactures and distributes an article which, if improperly used, is dangerous to human life is under a duty to apprise the purchasing public by labels or otherwise of the manner in which the article may be safely used"); *Webb v. Sandoz Chem. Works, Inc.*, 69 S.E.2d 689, 692 (Ga. Ct. App. 1952) (holding that plaintiff stated a cause of action for failure-to-warn sufficient to withstand motion to dismiss, but that evidence proffered later showed that defendant had provided adequate warning); *Love v. Wolf*, 249 Cal. App. 2d 822, 832 (Cal. Ct. App. 1967) (finding drug manufacturer liable for plaintiff's injuries based on both inadequate warning on the drug's label and overpromotion); *Reyes v. Wyeth Labs.*, 498 F.2d 1264 (5th Cir. 1974) (affirming holding that manufacturer could be liable for failure to warn consumer of adverse events and unreasonably dangerous conditions related to drug). And this failure-to-warn cause of action was expressly preserved in the most recent restatement: "A manufacturer of a prescription drug . . . is subject to liability for harm to persons caused by . . . [a] prescription drug . . . [that] is not reasonably safe due to inadequate instructions or warnings." Restatement (Third) of Torts: Prods. Liab. § 6 (1998)

As evidence that no one perceived that state tort litigation conflicted with federal drug regulation, pharmaceutical defendants in these suits generally did not even raise the defense of federal preemption. *See Riegel*, 128 S.Ct. at 1017 n.11 (Ginsburg, J., dissenting) ("Most defendants, it appears, raised no preemption defense to state tort suits involving FDA-approved drugs.") (collecting cases); *see also* cases cited *supra* 7 (in none of the afore-referenced cases did defendants raise a preemption defense).

Only since the late 1980s have drug company defendants regularly argued for preemption. *See, e.g., In re Tetracycline Cases*, 747 F. Supp. 543 (W.D. Mo. 1989) (rejecting defendant drug manufacturer's argument that the federal regulation of drug labels and package inserts preempted plaintiffs' claims). And, with few exceptions, courts have consistently rejected the defense of preemption in cases in which it was raised. *See Riegel*, 128 S.Ct. at 1018-19 & n.16 (Ginsburg, J., dissenting) ("Courts that have considered the question have overwhelmingly held that FDA approval of a new drug application does not preempt state tort suits.") (collecting cases); *Abbot by Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108, 1112 n.1 (4th Cir. 1988) ("The overwhelming majority of courts considering federal preemption of state law as regards vaccines have found no preemption.") (collecting cases); *see, e.g., id.* at 1111 (holding that in the FDCA "Congress did not intend, either expressly or impliedly, to preempt state law"); *Caraker v. Sandoz Pharms. Corp.*, 172 F. Supp. 2d 1018 (S.D. Ill. 2001); *Tobin v. Astra Pharm. Prods., Inc.*, 993 F.2d 528 (6th Cir. 1993); *Osburn v. Anchor Labs., Inc.*, 825 F.2d 908, 913 (5th Cir. 1987); *Feldman v. Lederle Labs.*, 479 A.2d 374 (N.J. 1984); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293,

1299 (D. Minn. 1988) ("The mere fact that the Cu-7 received FDA approval does not, by itself, indicate that Congress impliedly intended to preclude state tort actions against prescription drug manufacturers."). Even after the FDA, in the current administration, began to assert that state tort liability and federal regulation conflict, most courts continue to reject the preemption defense. *See, e.g., In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d 776, 785 (E.D. La. 2007); *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d. 230, 273-74 (E.D.N.Y. 2007); *Perry v. Novartis Pharm. Corp.*, 456 F. Supp. 2d 678 (E.D. Pa. 2006).

B. Congress and, Until Recently, the FDA Regarded State Tort Liability and Federal Regulation As Complementary.

1. Congress Has Shown No Intention To Preempt Common Law Tort Claims Concerning Prescription Drugs.

Congress enacted the FDCA in 1938 to remedy defects in the 1906 Act. Among other things, the earlier law had "fail[ed] to take cognizance of fraudulent statements covering food or drugs which are not in or upon the food or drug package." Secretary of Agriculture, *Annual Report for the Fiscal Year ended June 30, 1933*, 1, 13-14 (citing The Chief of the Bureau of Chemistry, *Annual Report 1917*), *quoted in Federal Food, Drug, and Cosmetic Act: A Statement of its Legislative Record* 24-25 (Charles Wesley Dunn, ed. 1938).

The revised Food and Drugs Act was first introduced in the Senate in 1933 as S. 1944. S. 1944

contained a provision titled Liability for Personal Injury, which stated: "A right of action for damages shall accrue to any person for injury or death proximately caused by a violation of this Act." *Id.* at 49 (citing S. 1944, as introduced in the 73d Congress, 1st Session, June 6, 1933). This provision, however, was not included in future versions of the act. Apparently, Congress decided not to create a federal cause of action for damages because, as witnesses testified, it was unnecessary: "[a] common law right of action [already] exists." *Hearings on S. 1944 Before a Subcomm. of the S. Comm. on Commerce*, 73d Cong., 2d Sess. 400 (1933) (statement of W.A. Hines); *id.* at 403 (statement of J.A. Ladds) ("This act should not attempt to modify or restate the common law with respect to personal injuries."); *see also Riegel*, 128 S.Ct. at 1017 n.10 (Ginsburg, J., dissenting) (quoting same). A key way to accomplish the FDCA's purpose of protecting the public was by retaining common law tort liability for personal injuries.

By passing the FDCA without a private right of action, Congress affirmed its intent that state tort actions would remain available to provide "judicial recourse for those injured." As this Court has observed in similar contexts:

> [Congress'] silence [regarding state law remedies for persons injured by radiation from a nuclear plant] takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct. It is difficult to believe that Congress would, without comment, remove all

> means of judicial recourse for those injured by illegal conduct.

Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984); *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 487 (1996) (citing same in construing 21 U.S.C. § 360k(a) of the Medical Device Amendments).

Congress revisited federal food and drug regulation in the 1962 Drug Amendments, which "shifted the burden of proof from FDA (which previously had to prove harm to keep a drug from being marketed) to manufacturers, who now were required to demonstrate both safety and efficacy prior to receipt of marketing approval." Institute of Medicine, Committee on the Assessment of the U.S. Drug Safety System, *The Future of Drug Safety: Promoting and Protecting the Health of the Public*, 152 (Alina Baciu, *et al.* eds. 2007) ("IOM Report") (citation omitted).

The 1962 amendments clarified the FDCA's intended relationship to state law. Congress included language explicitly *restricting* the potential preemptive effect of federal law to cases of "direct and positive conflict":

> Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating *any* provision of State law which would be valid in the absence of such amendments unless there is a *direct and positive conflict* between such amendments and such provision of State law.

Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962) (emphasis added). When Congress's express words provide "a 'reliable indicium of congressional intent with respect to state authority, there is no need to infer congressional intent to pre-empt state laws.'" *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992) (citation omitted).

Congress inserted the "direct and positive conflict" language in the 1962 Drug Amendments to limit claims of preemption. *See Thrall v. Wolfe*, 503 F.2d 313, 317 (7th Cir. 1974) (interpreting statute with *identical* "direct and positive conflict" language and concluding: "The section was doubtless inserted for the purpose of avoiding a claim of preemption"). "[D]ebates on the adoption of this provision expressly noted that the provision was consistent with the intention that federal law should not preempt in those fields where state food and drug laws are stronger." *Merrell Dow Pharms., Inc. v. Oxendine*, 649 A.2d 825, 828 n.3 (D.C. 1994) (citing 108 Cong. Rec. 21,083 (1962)). As the court below correctly concluded, the "plain language of the [FDCA] indicates that Congress did not intend to interfere with state prerogatives except where doing so is absolutely necessary, . . . and the plain language of the regulation [at issue] makes such interference unnecessary here." *See Levine v. Wyeth*, 944 A.2d 179, 191 (Vt. 2006).

Congress knows how to write an express preemption provision when it wants to: in subsequent amendments to the FDCA, Congress enacted express statutory preemption provisions applicable to medical devices, over-the-counter (OTC) drugs, and cosmetics. 21 U.S.C. § 360k(a) (1976); 21

U.S.C. § 379r (1997); 21 U.S.C. § 379s (1997).[2] But Congress never adopted any comparable preemptive language concerning prescription drugs, thereby further evidencing its intent not to preempt state law.

Most recently, in 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823. That act bolsters the FDA's authority to require a manufacturer to change a drug label if the agency becomes aware of information it believes should be included. 121 Stat. at 924 (to be codified at 21 U.S.C. §355 (o)(4)). To defuse claims that this expanded agency authority would lead to preemption, Congress included a "rule of construction" to make clear that the act did not "affect the responsibility of" a drug company "to maintain its label in accordance with existing requirements," including 21 C.F.R. §§ 201.80 (e) and 314.70(c). 121 Stat. at 925-26 (to be codified at 21 U.S.C. § 355(o)(4)(I)). These are the regulatory provisions invoked by many courts, including the court below, as grounds for rejecting drug company assertions of implied conflict preemption. Thus, here again, Congress indicated its intention not to preempt state tort law. *See* 153 Cong. Rec. S11833 (daily ed. Sept. 20, 2007) (statement of Sen. Kennedy) ("Congress has stated very clearly in the legislation that we do not intend the new authority being given to the FDA to preempt common law liability for a drug company's failure to warn its customers of health risks").

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[2] The preemption provisions applicable to OTC drugs and cosmetics include savings clauses that expressly exempt state product liability claims from preemption. 21 U.S.C. § 379r(e); 21 U.S.C. § 379s(d).

Congress has had numerous opportunities over the past seventy years to limit common law remedies for drug-related injuries, but has repeatedly declined to do so. Congress, instead, has emphasized that state law should not be preempted, except in cases where a "direct and positive conflict" exists.

2. The FDA, Prior to this Decade, Regarded State Tort Liability and Federal Regulation As Complementary.

The FDA itself also has recognized the utility of state products liability claims, and historically has not contended that such claims are preempted. In 1994, for example, when the FDA acted to prevent disclosure of the identities of patients and other persons involved with adverse event reports, the agency took pains to make clear that the action was "not intended to frustrate or impede tort litigation in this area. Indeed, FDA recognizes that product liability plays an important role in consumer protection." 59 Fed. Reg. 3944, 3948 (Jan. 27, 1994). That same year, the Chief Counsel of the FDA, Margaret Jane Porter, wrote to explain the agency's anti-preemption position in *Medtronic, Inc. v. Lohr*: "FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection." Margaret J. Porter, *The Lohr Decision: FDA Perspective and Position,* 52 Food & Drug. L.J. 7, 11 (1997).

On at least two occasions, the FDA has explicitly stated that its labeling regulations do not have preemptive effect. In a 2000 Notice of Proposed Rulemaking to revise those requirements, the agency

asserted that the proposed amendments "do[] not contain policies that have federalism implications or that *preempt* State law." 65 Fed. Reg. 81,082, 81,103 (Dec. 22, 2000) (emphasis added). Similarly, at oral argument in *Buckman Co. v. Plaintiff's Legal Committee,* Oral Arg. Official Trans., No.98-1768, 2000 WL 1801621 (Dec. 4, 2000), the Solicitor General's office, on behalf of the FDA, distinguished the fraud-on-the-FDA claim at issue in that case from traditional common law tort claims: "The fraud claim is preempted, but if there is negligent design, negligent manufacturing, failure to warn, common law malpractice, all of those claims are available" and are not preempted. *Buckman* Oral Arg. Official Trans., 2000 WL 1801621, at *21.

On yet other occasions, the FDA has expressed its view that state tort litigation does not conflict with or pose an obstacle to the agency's mission. In 1979, when the agency issued its final rule regarding prescription drug labeling, the rulemaking notice affirmed: "It is not the intent of the FDA to influence the civil tort liability of the manufacturer . . . ." 44 Fed. Reg. 37,434, 37,437 (Jun. 26, 1979). More explicitly, the rulemaking notice accompanying a 1998 final regulation on Patient Medication Guides stated that:

> FDA does not believe that the evolution of state tort law will cause the development of standards that would be at odds with the agency's regulations. FDA's regulations establish the minimal standards necessary, but were not intended to preclude the states from imposing additional labeling requirements. States may authorize

> additional labeling but they cannot reduce, alter, or eliminate FDA-required labeling.

63 Fed. Reg. 66,378, 66,384 (Dec. 1, 1998).

The FDA recognized that its regulatory efforts benefited from and were supplemented by state product liability litigation, such as that brought by Respondent here. As former FDA Commissioner David Kessler has written, it was

> the FDA's view that its regulatory efforts could comfortably coexist with state-law damages claims by consumers injured by drugs. As the agency saw it, state-law failure-to-warn litigation *did not* interfere with the agency's regulatory efforts. . . . State damages litigation helps uncover and assess risks that are not apparent to the agency during a drug's approval process. Until recently, in the FDA's view, this "feedback loop" enabled the agency to better do its job. The agency also wanted to avoid the "harsh implications" of eliminating "judicial recourse for consumers injured by defective" drugs.

David A. Kessler, M.D. & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 Geo. L.J. 461, 463 (2008) (emphasis added) (quoting Margaret J. Porter, *The Lohr Decision: FDA Perspective and Position*, 52 Food & Drug L.J. at 9).

Of course, in the past several years, the FDA's position has undergone a "seismic shift"; "[t]he agency now maintains that state law failure-to-warn cases threaten its ability to protect the public health." *Id.* But this Court should not ignore the agency's historic understanding that state tort litigation complemented the federal regulatory scheme.

C. State Tort Liability Supports Federal Regulation in Advancing Congress's Goal of Safe and Effective Pharmaceuticals.

Litigation is crucial to ensure the safety and effectiveness of drugs because, as Congress recognized, and the Institute of Medicine recently confirmed, FDA approval is not a guarantee of safety or efficacy and the FDA historically has lacked the tools to fully and adequately regulate drugs after they are on the market. *See* IOM Report, *supra*, 151-76. The FDA's reach is enormous, regulating "approximately $1 trillion in consumer products or 25 cents of every consumer dollar expended in this country annually." FDA Subcommittee on Science & Technology, *FDA Science & Mission at Risk* 1 (Nov. 2007) ("*Mission at Risk*"). Yet, as the FDA itself has concluded, the agency has "serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities." *Id.* at 2-3. The FDA is underfunded and overburdened, and needs "substantially increased resources in both funds and personnel" if it is to carry out the tasks assigned to it. IOM Report, *supra*, 197-98.

State common law provides an important supplement to this overtaxed regulatory system. *See*

In re Zyprexa Prods. Liab. Litig., 493 F. Supp. 2d. 571, 575 (E.D.N.Y. 2007) ("[L]awyers and their clients often find themselves serving as drug safety researchers of last resort.") (quotation omitted). Private tort litigation has "helped the medical community reassess drugs by bringing to light new information about adverse effects" and, "[i]n both the premarketing and postmarketing stages, lawsuits have helped uncover important and previously unavailable data about major adverse events." Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 JAMA 308 (Jan. 17, 2007).

Product liability claims, such as those brought by Respondent, work in concert with federal regulation, allowing the marketplace to provide an added financial incentive for manufacturers to make their products safe and effective as mandated by the FDCA. *See* John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 Miss. L.J. 825, 826 (1973); *see also* W. Kip Viscusi, *Reforming Products Liability* 66 (1991) ("The purpose of products liability is to fill the gaps left by market imperfections and to replicate the incentives that would have been generated had markets been functioning perfectly."). Moreover, by assessing risk retrospectively, product liability helps to compensate consumers for imperfect information. Steven P. Croley & Jon D. Hanson, *Rescuing the Revolution: The Revived Case for Enterprise Liability*, 91 Mich. L. Rev. 683, 707-08 (1993); State tort claims fulfill these roles directly, by providing remedies to people who suffer injuries from drugs, and also indirectly, by creating financial incentives for drug companies to update the warnings on their products' labels to reflect current knowledge about the dangers those products pose.

In addition, "tort law often informs regulatory decisions, and the FDA has often acted in response to information that has come to light in state damages litigation." Kessler & Vladeck, 96 Geo. L.J. at 477 (citing *Bates*, 544 U.S. at 451; *see also* Karen E. Lasser, *et al.*, *Timing of New Black Box Warnings & Withdrawals for Prescription Medications*, 287 JAMA 2215, 2218 (2002). The "legal system [has] played an important role in spurring change in regulatory or corporate procedures, as well as extending knowledge about drug risks by adding to the evidence available for evaluation by physicians, patients, and regulators." Kesselheim & Avorn, *supra*, at 310.

In all of these ways state tort claims complement federal regulation and further the purposes of the FDCA. *Cf. CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 668 (1993) ("In fact, the scheme of [state] negligence liability could just as easily complement [federal] regulations"); *Silkwood*, 464 U.S. at 264 (Blackmun, J. dissenting) (stating that tort damages "complement the federal regulatory standards, and are an implicit part of the federal regulatory scheme"). As this Court said in *Bates v. Dow Agrosciences LLC* about a similar statutory scheme: "Private remedies . . . would seem to aid, rather than hinder, the functioning of FIFRA . . . . FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings. . . . [T]ort suits can serve as a catalyst in this process." 544 U.S. at 451.

Petitioner's and the FDA's arguments that Respondent's claims are preempted ignore the long coexistence of state tort law and federal regulation

and the structural complementarity between the two. This Court should reject these arguments and, instead, reaffirm that state tort claims advance the FDCA's goal of consumer protection and the regulatory objective of prompt and effective warnings of serious health risks.

II. State Tort Law Has Always Taken Compliance with Federal Regulatory Standards Into Account In Determining Liability.

How is it possible that, for nearly a century, neither courts nor legislators nor federal regulators perceived any significant conflict between state tort liability for failure to warn and federal regulation of prescription drugs? One principal reason is that state tort law has always taken federal standards into account, permitting pharmaceutical companies to introduce their compliance with federal labeling requirements as evidence of non-negligence. But, at the same time, every state recognized that this evidence could be overcome by other evidence of negligence or willful wrongdoing. Such an approach ensures that there will be no "direct and positive conflict" between state tort liability standards and federal regulation.

A. Under the Traditional Common Law Rule, Compliance with Federal Regulations is Evidence of Non-Negligence, But Not Dispositive.

The traditional rule has been set forth clearly in both the second and third restatements of tort law. Section 288C of the Second Restatement provides: "Compliance with a legislative enactment or an

administrative regulation does not prevent a finding of negligence where a reasonable man would take additional precautions." Restatement (Second) of Torts § 288C (1965). The Third Restatement reiterates this principle in the context of products liability claims, while clarifying that regulatory compliance is relevant and admissible evidence to be considered:

> In connection with liability for defective design or inadequate instructions or warnings: . . . (b) a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but *such compliance does not preclude as a matter of law a finding of product defect.*

Restatement (Third) of Torts: Prods. Liab., § 4 (1998) (emphasis added).[3]

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[3] In a comment, the Restatement draws a sharp distinction between regulatory compliance and federal preemption. Section 4(b) of the Restatement:

> addresses the question of whether and to what extent, *as a matter of state tort law,* compliance with product safety statutes or administrative regulations affects liability for product defectiveness. . . .The safety statute or regulation may be a federal provision, but the decision to give it determinative effect is a state-law determination. In contrast, in federal preemption, the court decides *as a matter of federal law* that the relevant federal statute or

This treatment of regulatory compliance is a longstanding rule of common law. The principle was first prominently discussed by this Court in a case involving an accident at a railroad crossing, *Grand Trunk Railway Co. v. Ives*, 144 U.S. 408 (1892). As this Court observed:

> It is also held in many of the states (in fact the rule is well-nigh, if not quite, universal) that a railroad company, under certain circumstances, will not be held free from negligence, even though it may have complied literally with the terms of a statute prescribing certain signals to be given, and other precautions to be taken by it, for the safety of the traveling public at crossings.

Id. at 420-21; *see also Smith v. Maine Cent. R.R. Co.*, 32 A. 967, 970-71 (Me. 1895) ("[T]he statutes prescribing these special duties . . . do not constitute the sole measure of duty. The common law still requires the exercise of care and prudence commensurate with the degree of danger incurred. The statutes . . . do not release the company from the obligations to take such additional precautions as the peculiar circumstances of the case may demand."); *Catani v. Swift & Co.*, 95 A. 931, 933 (Pa. 1915) ("federal statutes providing for meat

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> regulation reflects, expressly or impliedly, the intent of Congress to displace state law, including state tort law, with the federal statute or regulation. . . . [T]he issue of defectiveness under state law is never reached.

Id., Comment e (emphasis added).

inspection by government officers do not relieve the packer from liability for damages [for breach of "common-law duty to sell only wholesome food"] where he has made no inspection nor taken any steps to ascertain for himself whether the meat sold by him is fit for food").

The rule has been applied repeatedly in failure-to-warn suits against pharmaceutical companies. *See, e.g., Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973) ("mere compliance with regulations or directives as to warnings, such as those issued by the [FDA] here, may not be sufficient to immunize the manufacturer or supplier of the drug from liability....[W]hen the manufacturer or supplier knows of, or has reason to know of, greater dangers not included in the warning, its duty to warn may not be fulfilled."); *McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522, 534 (Or. 1974) ("We hold that the warnings given by an ethical drug manufacturer may be found inadequate, '[a]lthough all of the government regulations and requirements have been satisfactorily met in the production and marketing of [the drug], and in the changes made in the literature'") (quoting *Yarrow v. Sterling Drug, Inc.*, 263 F. Supp. 159, 162 (D.S.D. 1967), *aff'd*, 408 F.2d 978 (8th Cir. 1969)); *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975) ("In North Carolina, as elsewhere, compliance with federal laws and regulations concerning a drug, though pertinent, does not in itself absolve a manufacturer of liability."); *Bristol-Myers Co. v. Gonzales*, 561 S.W.2d 801, 804 (Tex. 1978) ("fact that the package insert ... had been approved by the FDA did not relieve Bristol-Myers of its obligation to communicate an adequate warning to the users of this dangerous drug"); *MacDonald v. Ortho Pharm. Corp.*, 475

N.E.2d 65 (Mass. 1985) ("in instances where a trier of fact could reasonably conclude that a manufacturer's compliance with FDA labeling requirements or guidelines did not adequately apprise oral contraceptive users of inherent risks, the manufacturer should not be shielded from liability by such compliance."); *Wells v. Ortho Pharm. Corp.*, 788 F.2d 741, 746 (11th Cir. 1986) ("FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes"); *O'Gilvie v. Int'l Playtex, Inc.*, 821 F.2d 1438, 1443 (10th Cir. 1987).

Indeed, an instruction based on this rule was given to the jury in this case:

> You may consider evidence of compliance by Wyeth with FDA requirements in obtaining approval for the Phenergan warning. Compliance with FDA requirements does not by itself establish that the warning was adequate for purposes of this case. You must decide whether the instructions and warnings were adequate based upon all the evidence presented in this trial including evidence about the FDA process.

See Jury Instructions, Printed Case, vol. II, at 348. Wyeth did not object to this instruction. *Id.*

Many courts have explained the rule on the grounds that most product safety statutes and regulations set only minimum safety standards. *See, e.g., Stevens*, 507 P.2d at 661 ("The warnings

required by such agencies may be only minimal in nature"). But it would perhaps be more precise to say that such regulations set a proper, legally sufficient standard only in the absence of any special circumstances. Restatement (Second) of Torts, § 288C, Comm. *a*. ("Where there are no such special circumstances, the minimum standard prescribed by the legislation or regulation may be accepted by the triers of fact, or by the court as a matter of law, as sufficient for the occasion; but *if for any reason a reasonable man would take additional precautions, the provision does not preclude a finding that the actor should do so.*") (emphasis added). Thus, once a defendant has demonstrated that its conduct conformed to all regulatory requirements, it becomes incumbent on the plaintiff to come forward with evidence to support the proposition that, under the circumstances, more should have been done.

Numerous pharmaceutical cases demonstrate the application of this rule. Where no special circumstances existed, courts have granted judgment as a matter of law to defendants that complied with FDA labeling requirements. *See, e.g., Chambers v. G.D. Searle & Co.*, 441 F. Supp. 377, 384 (D. Md. 1975) (where defendant had "no other information . . . indicating greater risks or dangers" than was available to FDA team that had developed package insert for oral contraceptive, it was reasonable for defendant to "rely on warnings approved by the entire group"); *Wolfgruber v. Upjohn Co.*, 423 N.Y.S.2d 95, 97-98 (App. Div. 1979) (summary judgment appropriate where "[t]he warning given was adequate by any standard and the plaintiff as a doctor knew the risks of taking this particular drug whose side effects were those specifically warned against as fully as defendant was able."); *Ramirez v.*

Plough, Inc., 863 P.2d 167, 175 (Cal. 1993) (Manufacturer of aspirin was not negligent as a matter of law for failing to include warnings in Spanish, where "FDA's regulations abundantly demonstrate its sensitivity to the issue of foreign-language labeling, and yet the FDA regulations do not require it").

In many other cases, where plaintiffs presented evidence that a reasonable drug company should have done more to warn of the dangers posed by its product, courts have concluded that the issue of negligence was for the jury. *Bristol-Myers Co. v. Gonzales* presents what may be the paradigmatic case: there officials at the defendant drug company knew "that the approved insert did not adequately warn of potential dangers . . . long before the inadequacy became known to the government." 561 S.W.2d at 804. But such plaintiffs' evidence has taken numerous other forms. In *Salmon*, for example, there was evidence that the defendant had resisted an FDA suggestion to strengthen the warning on an antibiotic, despite knowledge that physicians were ignoring the existing warning and using the drug carelessly to treat minor infections. 520 F.2d at 1363. In *Brochu v. Ortho Pharm. Corp.*, the court of appeals affirmed a jury verdict against a manufacturer of oral contraceptives that used the same label warnings on all of its products, even though it knew that the risk of stroke was far greater with its high-estrogen-dose pills. 642 F.2d 652, 657-59 (1st Cir. 1981). In *Hoffman v. Sterling Drug, Inc.*, the defendant drug company promoted the use of its drug for the treatment of lupus, an indication that had not been approved by the FDA. 485 F.2d 132, 138 (3d Cir. 1973). In *Toole v. Richardson-Merrell, Inc.*, the drug company's submission of false and

misleading reports to the FDA gave rise to a "presumption of negligence". 251 Cal.App. 2d 689, 702-04 (Cal. App. 1967). And, in a number of cases, courts have held that overpromotion of a drug by the manufacturer may have undermined the effectiveness of its label warnings and created a triable issue regarding negligence. *See, e.g., Whitley v. Cubberly*, 210 S.E.2d 289, 291-92 (N.C. App. 1974); *Stevens v. Parke, Davis & Co.*, 507 P.2d at 662; *Incollingo v. Ewing*, 282 A.2d 206, 220 (Pa. 1971); *Love v. Wolf*, 226 Cal. App. 2d 378, 396 (Cal. Ct. App. 1964).

Respondent Diana Levine offered comparable evidence at trial. She introduced evidence that, although the FDA was concerned about the greater dangers of inadvertent arterial exposure associated with intravenous (IV) administration of Phenergan, as opposed to intramuscular administration, the agency never directly considered or addressed the relative merits of IV push versus IV drip as methods of IV administration. *See* Pet. App. 167a-168a (Phenergan label); Resp. Br. at 10-14. In addition, plaintiff presented expert testimony at trial that Pfizer, the manufacturer of Vistaril, a product posing risks similar to Phenergan when administered intravenously, voluntarily modified its label around 1970 to permit only intramuscular administration and to prohibit IV use. Trial Tr., Mar. 8, 2004, Vol. I, at pp. 232-33 (testimony of Dr. Harold Green). This was more than sufficient evidence for a jury to decide that Wyeth should have "take[n] additional precautions."

Thus, since long before there was any federal regulation of prescription drugs, the legal principle has been well established that compliance with

regulatory requirements does not preclude a finding of negligence. And that has remained the predominant common law rule, through each revision of federal food and drug law, without objection from Congress or, until recently, the FDA.

B. Virtually Every State, and the Congress, Have Declined to Treat Regulatory Compliance as Conclusive of Non-Negligence.

As the administrative state—including the federal regulation of prescription drugs—has grown more comprehensive and complex, some have asserted that this traditional common law treatment of regulatory compliance was insufficient and have argued for a strengthened regulatory compliance defense that would, under certain circumstances, preclude a finding of liability. *See, e.g.*, Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 Colum. L. Rev. 277 (1985); Richard A. Epstein, *Legal Liability for Medical Innovation*, 8 Cardozo L.Rev. 1139 (1987). Despite this advocacy, virtually every state, as well as the Congress, has declined to make regulatory compliance a dispositive affirmative defense.

Many state legislatures have considered whether to adopt a regulatory compliance affirmative defense, but only one—the state of Michigan—has actually done so.[4] A handful of states have passed laws that

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[4] Michigan, alone among the states, has determined that compliance with FDA labeling requirements should bar virtually any liability for failure to warn. Mich. Comp. Laws Ann. § 600.2946(5) provides that a drug "is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the

create a presumption that a defendant who satisfies regulatory requirements is not negligent, but make that presumption rebuttable.[5] Such statutes do not depart much, if at all, from the common law rule: a plaintiff may still rebut the presumption by presenting evidence that, under the circumstances, a reasonable defendant would have gone further.

A smaller number of states have decided that compliance with FDA requirements should be a bar to punitive damages, absent a showing that the defendant defrauded or withheld information from the agency.[6] These statutes, however, do not limit a

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[FDA], and the drug and its labeling were in compliance with the [FDA's] approval at the time the drug left the control of the manufacturer or seller." The statute does leave open the possibility that a drug company may be liable if it withheld or misrepresented information that it was required to submit to the FDA, *id.* § 600.2946(5)(a), though courts have divided about whether this so-called "fraud" exception is preempted under this Court's decision in *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001). *Compare Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004), *with DeSiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), *aff'd by equally divided court sub nom. Warner-Lambert Co., LLC v. Kent*, 128 S.Ct. 1168 (2008).

[5] *See* Colo. Rev. Stat. § 13-21-403 (1)(b); Ind. Code Ann. § 34-20-5-1; Kan. Stat. Ann. § 60-3304; Ky. Rev. Stat. Ann. § 411.310(2); Tenn. Code Ann. § 29-28-104; Utah Code Ann. § 78B-6-703(2). New Jersey and Texas also create such a rebuttable presumption specifically for FDA-approved warnings. *See* N.J. Stat. Ann. § 2A:58C-4; Tex. Civ. Prac. & Rem. Code Ann. § 82.007.

[6] *See* Ariz. Rev. Stat. Ann. § 12-701; N.J. Stat. Ann. § 2A:58C-5(c); Ohio Rev. Code Ann. § 2307.80(C)(1); Or. Rev. Stat. § 30.927; Utah Code Ann. § 78B-8-203; *cf.* Colo. Rev. Stat. § 13-64-302.5(5)(a) (limiting protection against punitive damages to health care professionals).

drug company defendant's exposure to compensatory damages if a jury finds fault with its conduct.

Thus, even after careful legislative consideration, forty-nine of the fifty states have rejected a regulatory compliance affirmative defense to liability for failure to warn of the dangers posed by prescription drugs.

Congress has been even less willing to treat federal regulatory compliance as a barrier to state tort liability. In 1977, legislation was proposed in the Senate that would have given manufacturers a defense to damage claims if they complied with federal product safety standards, S. 403, 95th Cong., 1st Sess. § 601 (1977), but no action was taken on it. That same year, a bill introduced in the House would have created a rebuttable presumption that a product that complied with applicable standards was not negligently or defectively designed, H.R. 6300, 95th Cong., 1st Sess. § 8(a)(3), but no action was taken. Similar bills, H.R. 5626 and H.R. 7284, introduced in 1979 and 1982 respectively, met the same fate.

In the 1980s and early 1990s, a number of bills were introduced that would have established a regulatory compliance defense to punitive damages, sometimes limited to drug and device companies and airplane manufacturers, but which would not have affected compensatory damage claims. *See, e.g.*, S. 1999, 99th Cong., 1st Sess. § 306(c) (1985); S. 2760, 99th Cong., 2nd Sess. § 303(c)(1) (1986); S. 640, 102d Cong., 1st Sess. § 303(c) (1991); S. 687, 103d Cong., 1st Sess. § 203(b)(1) (1993). While several of these bills made it to the Senate floor, none was passed. *See generally*, Richard C. Ausness, *The Case for a*

"Strong" Regulatory Compliance Defense, 55 Md. L. Rev. 1210, 1248-51 (1996). The House of Representatives did once adopt a provision immunizing drug companies from punitive damages for FDA-approved drugs as part of sweeping tort reform legislation, H.R. 956, 104th Cong., 1st Sess. § 201(f) (as passed by House, Mar. 10, 1995), but that provision was dropped in conference to avoid likely rejection in the Senate, and the bill was vetoed by President Clinton. *See* Teresa Moran Schwartz, *Regulatory Standards and Products Liability: Striking the Right Balance Between the Two,* 30 U. Mich. J.L. Ref. 431, 441 n.50 (1997) ("*Striking the Right Balance*").

Thus, despite numerous opportunities to consider the issue, Congress has been unwilling to enact even the more limited restrictions on state tort liability—the rebuttable presumption and bar to punitive damages—that have been adopted by some states. Congress has shown no interest whatsoever in going further and making compliance with FDA regulations a complete defense to liability for failure to warn.

C. An FDA Compliance Defense Would Pose Many Problems.

Congress and the states had good reason for rejecting a regulatory compliance defense for prescription drugs. Such a defense would necessarily be narrow and difficult to apply, would place excessive reliance on an underfinanced FDA for drug safety, would undermine incentives for manufacturers to apply to the FDA to strengthen their label warnings, would—if effected by the federal government—infringe upon state

sovereignty, and would leave persons injured by drugs with inadequate warnings without any remedy for their injuries. *See generally,* Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case,* 30 U. Mich. J.L. Ref. 461 (1997); Schwartz, *supra, Striking the Right Balance,* 30 U. Mich. J.L. Ref. 431; Robert L. Rabin, *Reassessing Regulatory Compliance,* 88 Geo. L.J. 2049 (2000).

Such an affirmative defense would be narrow and difficult to apply for many reasons. First, courts would have to determine whether the precise question in the underlying tort litigation had been considered and resolved by the FDA. Teresa Moran Schwartz, *The Role of Federal Safety Regulations In Products Liability Actions,* 41 Vand. L. Rev. 1121, 1130-31 (1988) ("If an agency has not addressed specifically the matter before the court, the argument for judicial deference fails."). Next, defendants would have to demonstrate not simply that their drug and label had been approved by the FDA, but also that they had complied with all regulatory requirements regarding both pre-approval testing and post-approval marketing, to ensure that the agency had all necessary information when rendering its judgment; this would significantly limit the defense's utility as a tool to simplify tort litigation. Green, 30 U. Mich. J.L. Ref. at 481-82, 488-90. Moreover, an FDA compliance defense would have virtually no applicability to the majority of failure-to-warn cases, which involve risks discovered after product approval,[7] off-label uses,[8] or

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[7] Most failure-to-warn cases involve "risks that emerged after the drugs were approved by the FDA and made available to the public." *Id.* at 473; *see also* GAO, *FDA Drug Review: Post-Approval Risks 1976-85* 3 (1990) (over half of approved drugs had serious risks not detected until after FDA approval).

allegations of overpromotion, all contexts in which the FDA cannot have weighed the optimal balance between over- and under-warning. Rabin, 88 Geo. L. Rev. at 2077-82.

A compliance defense would also place excessive reliance on the FDA. Even if the agency had adequate resources, there would be problems of regulatory obsolescence and regulatory lag, the time it takes for the FDA to process and act upon new information. Moreover, the agency is dependent on drug companies for information and such companies have substantial influence upon the drug approval process. And, report after report in recent years has concluded that the FDA is under-resourced and under-staffed to ensure the currency and adequacy of existing drug labels. *See,* Schwartz, *Striking the Right Balance,* 30 U. Mich. J.L. Ref. at 443-46; IOM Report, *supra,* 197-98; *Mission at Risk, supra,* 2-3.

Third, a regulatory compliance defense would have a negative effect on the adequacy of FDA labeling requirements; a defense to tort liability would give drug companies strong incentives to resist efforts to strengthen the warnings on their products. Schwartz, *Striking the Right Balance,* 30

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[6] Estimates are that close to half of all American drug prescriptions are written for indications that have not been approved by the FDA. *See* Kaspar J. Stoffelmayr, *Products Liability and "Off-Label" Uses of Prescription Drugs,* 63 U. Chi. L. Rev. 275, 278 (1996). As the agency has observed: "Once a drug product has been approved for marketing, a physician may, in treating patients, prescribe the drug for uses not included in the drug's approved labeling. The primary legal constraints in that situation are State laws on medical practice and *products liability law.*" 48 Fed. Reg. 26,720, 26,733 (June 9, 1983) (emphasis added).

U. Mich. J.L. Ref. at 452-53; Green, 30 U. Mich. J.L. Ref. at 501-02.

Fourth, displacement of state tort law by the federal government would be a significant infringement on state sovereignty. As this Court has acknowledged repeatedly, "regulation of health and safety matters is primarily, and historically, a matter of local concern," within the police powers of the states. *Hillsborough Cty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1982). The states have experimented with various approaches to address the relationship between regulatory compliance and tort law.[9] To override the states' ability to define that relationship in their civil justice systems would deprive states of their autonomy and do serious harm to our federalism. Rabin, 88 Geo. L. Rev. at 2057, 2073-74.

Finally, and most importantly, a regulatory compliance defense would leave those persons injured by drug products, such as Diana Levine, remediless, regardless of the negligence of the drugmaker or the inadequacy of the warnings that had been approved by the FDA. *Id.* at 2073.

Given all these problems, "it is not so surprising that the regulatory compliance defense has never captured the widespread assent of courts and

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[9] In Justice Brandeis' famous words: "It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting).

commentators," *id.* at 2084, or of state legislatures and the Congress.

III. Because State Tort Law Takes Appropriate Account of Compliance with FDA Labeling Requirements, There Can Be No "Direct and Positive Conflict" Between State and Federal Law That Would Justify Preemption.

Wyeth and its *amici*, including the FDA, now seek from this Court what they have been unable to gain from state courts, state legislatures, and the Congress: a broad and blunt regulatory compliance affirmative defense under the guise of implied conflict preemption. Forty-nine of the fifty states have rejected the call for such a defense. They have found state tort law and federal regulation to be complementary systems that can comfortably co-exist. Likewise, Congress has shown no interest in adopting a national compliance affirmative defense, nor has it expressed any intention to preempt state tort remedies against drug companies. To the contrary, Congress has made clear its position that there should be no preemption of state law, except in cases of "direct and positive conflict."

There is no such conflict here. Under the traditional, common law treatment of regulatory compliance, a person injured by a prescription drug will not prevail on a failure-to-warn claim against a drug company that complied with its FDA labeling obligations, unless she can come forward, as Diana Levine did, with evidence that under the circumstances a reasonable drug company would have done more to warn of the dangers posed by its

product. Where such special circumstances exist, a determination of state tort liability against the company cannot be said to be in "direct and positive conflict" with FDA labeling determinations.

CONCLUSION

For the foregoing reasons, *amicus curiae* the American Association for Justice urges this Court to affirm the judgment of the Vermont Supreme Court.

Respectfully Submitted,

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